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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ASTRAZENECA LP,	)	CIVIL ACTION NO.
KBI-E INC., and POZEN INC.,	)	
Plaintiffs,	)	<b>COMPLAINT FOR</b>
v.	)	<b>PATENT INFRINGEMENT</b>
ANCHEN PHARMACEUTICALS, INC. and	)	
ANCHEN, INC.	)	
Defendants.	)	
	)	

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, “Plaintiffs”), by their attorneys, for their Complaint against Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc. (collectively, “Defendants”), allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application (“ANDA”) No. 202767 filed by or for the benefit of Defendants with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VIMOVO® pharmaceutical products that are sold in the United States.

**THE PARTIES**

2. Plaintiff AstraZeneca AB (“AZ AB”) is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca LP (“AZ LP”) is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff KBI-E Inc. (“KBI-E”) is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware.

5. Plaintiff Pozen Inc. (“Pozen”) is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

6. On information and belief, Defendant Anchen Pharmaceuticals, Inc. (“Anchen Pharmaceuticals”) is a corporation operating and existing under the laws of California, having its

principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

7. On information and belief, Defendant Anchen, Inc., (“Anchen, Inc.”) is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

8. On information and belief, Anchen Pharmaceuticals is a wholly-owned subsidiary of Anchen, Inc.

## **BACKGROUND**

### **The NDA**

9. AZ LP is the holder of New Drug Application (“NDA”) No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

10. VIMOVO® is a prescription drug approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO®.

### **The Patents-In-Suit**

11. United States Patent No. 6,926,907 (“the ’907 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued by the United States Patent and Trademark Office on August 9, 2005. The claims of the ’907 patent are directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and a NSAID (claims 1-21, and 53-55), and a method of treating a patient for pain or

inflammation comprising administration of the aforementioned compositions (claims 22-52). A true and correct copy of the '907 patent is attached as Exhibit A.

12. Pozen owns the '907 patent by assignment. AZ AB is Pozen's exclusive licensee under the '907 patent. The '907 patent will expire on February 28, 2023.

13. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the United States Patent and Trademark Office on April 9, 2002. The claims of the '085 patent are directed to magnesium salts of S-omeprazole trihydrate (claims 1-3), processes for the preparation of the aforementioned magnesium salts of S-omeprazole trihydrate (claims 4-10), pharmaceutical compositions comprising the aforementioned magnesium salts of S-omeprazole trihydrate (claim 11), and methods of treating gastric acid related conditions comprising administration of the aforementioned magnesium salts of S-omeprazole trihydrate (claim 12). A true and correct copy of the '085 patent is attached as Exhibit B.

14. AZ AB owns the '085 patent by assignment. KBI-E is AZ AB's exclusive licensee under the '085 patent. The '085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '085 patent will expire on November 25, 2018.

15. United States Patent No. 7,411,070 ("the '070 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the United States Patent and Trademark Office on August 12, 2008. The claims of the '070 patent are directed to magnesium salts of S-omeprazole trihydrate (claims 1-2), and processes for the preparation of the aforementioned magnesium salts of S-omeprazole trihydrate (claims 3-4). A true and correct copy of the '070 patent is attached as Exhibit C.

16. AZ AB owns the '070 patent by assignment. KBI-E is AZ AB's exclusive

licensee under the '070 patent. The '070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '070 patent will expire on November 25, 2018.

17. United States Patent No. 7,745,466 ("the '466 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the United States Patent and Trademark Office on June 29, 2010. The claims of the '466 patent are directed to pharmaceutical compositions comprising a first and second active ingredient and a pharmaceutically acceptable carrier, wherein the first active ingredient is a magnesium salt of S-omeprazole trihydrate (claims 1-15), and methods for treating gastric acid related conditions comprising administration of the aforementioned compositions (claim 16). A true and correct copy of the '466 patent is attached as Exhibit D.

18. AZ AB owns the '466 patent by assignment. KBI-E is AZ AB's exclusive licensee under the '466 patent. The '466 patent will expire on October 13, 2018.

### **The ANDA**

19. On information and belief, Anchen Pharmaceuticals filed ANDA No. 202767 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for Anchen Pharmaceuticals and Anchen, Inc. to commercially manufacture, use, import, offer for sale, and sell in the United States naproxen and esomeprazole magnesium delayed release tablets in two dosage forms: 500 mg (naproxen)/20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) ("Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets"), which are generic versions of Plaintiffs' VIMOVO® Delayed Release Tablets in 500 mg (naproxen)/20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

20. By letter dated September 16, 2011 (the "ANDA Notice Letter"), Anchen

Pharmaceuticals notified Plaintiffs that it had filed ANDA No. 202767 seeking approval to market Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets and was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

**JURISDICTION AND VENUE**

21. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

22. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing pharmaceutical products.

23. On information and belief, Anchen, Inc., either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

24. On information and belief, Anchen Pharmaceuticals, with the assistance and/or at the direction of Anchen, Inc. develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

25. On information and belief, Defendants acted in concert to develop Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, and to seek approval from the FDA to sell Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets throughout the United States, including within this judicial district.

26. On information and belief, both Anchen Pharmaceuticals and Anchen, Inc. have been and are engaging in activities directed toward infringement of the '907 Patent, the '085

patent, the ‘070 patent, and the ‘466 patent (collectively “the patents-in-suit”) by, *inter alia*, preparing and/or submitting ANDA No. 202767 seeking FDA approval to market Anchen’s Naproxen and Esomeprazole Magnesium Delayed Release Tablets. As stated in the ANDA Notice Letter, Defendants intend to market Anchen’s Naproxen and Esomeprazole Magnesium Delayed Release Tablets before expiration of the patents-in-suit. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 202767 from Anchen Pharmaceuticals.

27. In its ANDA Notice Letter, Anchen Pharmaceuticals stated that the name and address of its agent in the United States authorized to accept service of process for purposes of an infringement action based upon its ANDA Notice Letter is Margaret Choy of Anchen Pharmaceuticals, Inc., 9601 Jeronimo Road, Irvine, California, 92618.

28. Upon information and belief, Anchen, Inc. is subject to personal jurisdiction in New Jersey because, among other things, Anchen, Inc. has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. Upon information and belief, Anchen, Inc. manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs’ claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

29. Upon information and belief, Anchen Pharmaceuticals is subject to personal jurisdiction in New Jersey because, among other things, Anchen Pharmaceuticals has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. Upon information and belief, Anchen Pharmaceuticals manufactures, markets, and/or sells generic drugs throughout the United States

and within the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

30. On information and belief Anchen Pharmaceuticals has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., AstraZeneca Pharms. LP and AstraZeneca UK Limited v. Anchen Pharms., Inc. and Anchen, Inc.*, Civ. Action No. 3:10-cv-01835-JAP-DEA (D.N.J.); *Abbott Labs. and Fournier Labs. Ireland, LTD. v. Anchen Pharms., Inc.*, Civ. Action No. 2:10-cv-03015-DMC-CCC (D.N.J.); and *Schering Corp. v. Anchen Pharms., Inc.*, Civ. Action No. 3:07-cv-05649-MLC-TJB (D.N.J.).

31. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. are closely related in that both companies conduct business in the generic pharmaceutical industry; employees from both companies are intermingled; both companies share the same address; both companies share officers and employees; and the companies collaborate in the manufacture, marketing, and sale of pharmaceutical products, including generic drug products manufactured and sold throughout the United States pursuant to approved abbreviated new drug applications.

32. In addition, during the prosecution of Anchen Pharmaceuticals' trademark application for the word mark ANCHEN (serial no. 77051871), representatives for Anchen Pharmaceuticals stated that "Anchen Pharmaceuticals, Inc. and Anchen Incorporated, though separate legal entities, constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods."

33. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 202767, this Court has

personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

34. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

**COUNT I**

**(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))**

35. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

36. Defendants have infringed one or more claims of the '907 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, by filing their ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '907 patent.

37. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation into the United States of Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved by the FDA, will constitute direct infringement of claims 1, 5, 9-17, and 53-55 of the '907 patent.

38. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved, will be prescribed and administered to human patients to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with NSAIDs, which uses will constitute direct infringement of claims 22, 23, 35, 48, and 50-52 of the '907 patent. On information and belief, these uses will occur with Defendants' specific intent, knowledge and encouragement. On information and belief,

Defendants will actively induce, encourage, aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '907 patent.

39. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are especially made or especially adapted to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs) by inhibiting gastric acid secretion. On information and belief, Defendants are aware that Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are so made or so adapted. On information and belief, Defendants are aware that Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '907 patent.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

## **COUNT II**

### **(INFRINGEMENT OF THE '085 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))**

41. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

42. By their ANDA Notice Letter, Defendants informed Plaintiffs that as part of their ANDA they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '085 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '085 patent, "is invalid or

will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation.”

43. On information and belief, at the time the ANDA Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 42, above.

44. Defendants’ ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 42 above), does not allege invalidity of any claims of the ’085 patent.

45. Defendants have infringed one or more claims of the ’085 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, by filing their ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the ’085 patent.

46. On information and belief, Anchen’s Naproxen and Esomeprazole Magnesium Delayed Release Tablets contain a magnesium salt of esomeprazole trihydrate as claimed by the ’085 patent.

47. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved, will be prescribed and administered to human patients in the form of a pharmaceutical formulation and in a therapeutically effective amount to treat gastric acid related conditions, which uses will constitute direct infringement of one or more claims of the '085 patent. On information and belief, these uses will occur at Defendants' active behest and with its intent, knowledge and encouragement. On information and belief, Defendants will actively induce, encourage, aid and abet this prescription and administration with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '085 patent.

48. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are especially made or especially adapted to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs) by inhibiting gastric acid secretion. On information and belief, Defendants are aware that Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are so made or so adapted. On information and belief, Defendants are aware that Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

49. On information and belief, the manufacture, use and sale of Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets infringe the '085 patent claims.

50. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

### **COUNT III**

#### **(INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))**

51. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

52. By their ANDA Notice Letter, Defendants informed Plaintiffs that as part of their ANDA they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) with respect to the ’070 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’070 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation.”

53. On information and belief, at the time the ANDA Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 52, above.

54. Defendants’ ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 52 above), does not

allege invalidity of any claims of the '070 patent.

55. Defendants have infringed one or more claims of the '070 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, by filing their ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '070 patent.

56. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets contain a magnesium salt of esomeprazole trihydrate as claimed by the '070 patent.

57. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are manufactured by a process comprised of treating a magnesium salt of esomeprazole with water, as claimed by the '070 patent.

58. On information and belief, the manufacture, use and sale of Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets infringe the '070 patent claims.

59. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

#### **COUNT IV**

##### **(INFRINGEMENT OF THE '466 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))**

60. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

61. By their ANDA Notice Letter, Defendants informed Plaintiffs that as part of their ANDA they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '466 patent. This statutory section requires, *inter alia*,

certification by the ANDA applicant that the subject patent, here the '466 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

62. On information and belief, at the time the ANDA Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 61, above.

63. Defendants' ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 61 above), does not allege invalidity of any claims of the '466 patent.

64. Defendants have infringed one or more claims of the '466 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, by filing their ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '466 patent.

65. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets contain a magnesium salt of esomeprazole trihydrate as claimed by the

'466 patent.

66. On information and belief, Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets are especially made or especially adapted to treat gastric acid related conditions via the administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole magnesium trihydrate and a non-steroidal anti-inflammatory agent. On information and belief, Defendants are aware that its naproxen and esomeprazole magnesium delayed release tablets are so made or so adapted. On information and belief, Defendants are aware that Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '466 patent.

67. On information and belief, the manufacture, use and sale of Anchen's Naproxen and Esomeprazole Magnesium Delayed Release Tablets infringe the '466 patent claims.

68. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

#### **PRAAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that the claims of the patents-in-suit are valid and enforceable;
- B. A judgment that the submission of ANDA No. 202767 by Defendants infringes one or more claims of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A);
- C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 202767 shall be no earlier than the later of the expiration date of the last to expire of the patents-in-suit or any later exclusivity to which

Plaintiffs are or become entitled;

- D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 202767 no earlier than the later of the expiration date of the last to expire of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;
- E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- F. Costs and expenses in this action; and
- G. Such further and other relief as this Court may deem just and proper.

Dated: October 28, 2011  
By:

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of *ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC. v. DR. REDDY'S LABS. INC. and DR. REDDY'S LABS. LTD.*, Civil Action No. 3:11-cv-02317-JAP-DEA (D.N.J.) (the “VIMOVO® DRL case”) and *ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., v. LUPIN LTD. and LUPIN PHARMS. INC.*, Civil Action No. 3:11-cv-04275 (JAP)(DEA) (the “VIMOVO® Lupin case”). The VIMOVO® DRL case and the VIMOVO® Lupin case involve the same patents and the same product as the matter in controversy, have been assigned to Hon. Joel A. Pisano, U.S.D.J. The VIMOVO® DRL and Lupin cases have been consolidated for discovery purposes.

Furthermore, I certify that the matter in controversy is related to the subject matter of the following active case (the “NEXIUM® case”) currently pending before Judge Pisano: *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC. v. LUPIN LTD. and LUPIN PHARMS., INC.*, Civil Action No. 3:09-cv-05404-JAP-TJB (D.N.J.). NEXIUM® is a product marketed by AstraZeneca that contains esomeprazole magnesium. The product involved in the matter in controversy -- VIMOVO® -- contains naproxen and esomeprazole magnesium (the active ingredient in NEXIUM®). The NEXIUM® case involves one or more patents asserted in the matter in controversy.

Therefore, for the sake of judicial economy and with regard to Judge Pisano’s familiarity with the NEXIUM® patents asserted in the matter in controversy, Plaintiffs believe the VIMOVO® DRL case, VIMOVO® Lupin case, the NEXIUM® case, and the matter in controversy are all related. Accordingly, Plaintiffs respectfully request that the matter in controversy be assigned to Judge Pisano.

Dated: October 28, 2011

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